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PATENT

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Applicant:	Gregory Grabowski, Hong Du	: Paper No:	
Serial No.	09/775,517	: Group Art Unit:	1651
Filed:	February 2, 2001	: Examiner:	Weber
For:	Lipid Hydrolysis Therapy for Atherosclerosis and Related Diseases		

RESPONSE TO RESTRICTION REQUIREMENT

The Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action, dated December 10, 2002, setting forth a restriction requirement in the above patent application, please consider the following remarks.

In the Office Action, the Examiner has requested that the Applicant make an election between the following six groups of claims, which the Examiner contends represent six independent or distinct inventions:

I. Claims 1-18, drawn to a method of reducing atherosclerotic plaque in a mammal with lysosomal acid lipase, classified in class 424, subclass 94.6;

II. Claims 19-36 and 66-68, drawn to a method of treating atherosclerosis in a mammal with lysosomal acid lipase, classified in class 424, subclass 94.6;

III. Claims 37-50, drawn to lysosomal acid lipase and pharmaceutical compositions thereof, classified in class 435, subclass 197+;

IV. Claims 51-63, drawn to gene therapy with the gene for lysosomal acid lipase, classified in class 800, subclass 23;

V. Claim 64, drawn to a method of treating Wolman's disease with lysosomal acid lipase, classified in class 424, subclass 94.6;

VI. Claim 65, drawn to a method of treating Cholesteryl ester storage disease with lysosomal acid lipase, classified in class 424, subclass 94.6.

Applicants respectfully traverse the restriction requirement for the following reasons. The Examiner contends that the six groups of claims represent six distinct inventions. The Examiner initially concedes that inventions III and I, II, V and VI are related as product and process of use. However, the Examiner also maintains that these inventions can be shown to be distinct if the product, as claimed, can be used in a materially different process for using that product (MPEP §806.05(h)). Invention III is drawn to lysosomal acid lipase and pharmaceutical compositions thereof. Invention I is drawn to a method of reducing atherosclerotic plaque in a mammal with lysosomal acid lipase. Invention II is drawn to a method of treating atherosclerosis in a mammal with lysosomal acid lipase. Invention V is drawn to a method of treating Wolman's disease with lysosomal acid lipase. Invention VI is drawn to a method of treating Cholesteryl ester storage disease with lysosomal acid lipase. In the instant case, the Examiner argues that the product of Group III can be used in the processes of Groups I, II, V and VI.

The inventions of groups I, II, V and VI (claims 1-18, 19-36 and 66-68, 64 and 65) all define methods of treatment using lysosomal acid lipase, while invention III relates to lysosomal acid lipase and pharmaceutical compositions thereof. Therefore, if a complete search is one on invention III, which is directed to lysosomal acid lipase (claims 37-50), inventions I, II, V and VI will also be searched, since all of these claims relate to a method of use for lysosomal acid lipase.

MPEP §803 indicates that even if a patent application contains independent and distinct inventions, those inventions should be considered together by the Examiner if he can do so without any undue burden. Therefore, even assuming arguendo that the claims of inventions III and I, II, V and VI do define five separate inventions, the Examiner can consider all of them without placing himself under an undue burden since they all relate to methods of treatment using lysosomal acid lipase and pharmaceutical compositions thereof. A search of invention III will, by necessity, include inventions I, II, V and VI, so the Examiner is not placed under an additional burden by considering all of these claims together. Therefore, the claims of inventions I, II, III, V and VI of the present application should be considered together.

The Examiner argues that the inventions of groups I, II, V and VI (claims 1-18; claims 9-36 and 66-68; claim 64; and claim 65) are unrelated and represent different inventions because these groups are drawn to the treatment of different diseases or disease states and that the treatment of one disease does not immediately suggest the treatment of others. The inventions of groups I, II, V and VI all define methods of treatment using lysosomal acid lipase and pharmaceutical compositions thereof. As previously stated, MPEP §803 indicates that even if a patent application contains independent and distinct inventions, those inventions should be considered together by the Examiner if he can do so without any undue burden. Therefore, even assuming arguendo that the claims of inventions I, II, V and VI do define four separate inventions, the Examiner can consider all of them without placing himself under an undue burden since they all relate to methods of treatment using lysosomal acid lipase and pharmaceutical compositions thereof. Therefore, the claims of inventions I, II, V and VI of the present application should be considered together.

In addition, a search of the *use* of lysosomal acid lipase for the treatment of atherosclerotic plaque, as described in invention I (claims 1-18) would necessarily include a very large part (if not all) of the search required for claims 19-36, 66-68 (invention II, a method of treating atherosclerosis, which is in fact characterized by a build-up of atherosclerotic plaque); and claims 64 and 65 (the invention of groups V and VI), which are directed to other treatments using lysosomal acid lipase and pharmaceutical compositions thereof. In addition, as indicated by the Examiner, inventions I, II, V and VI would all require a search of the same class and subclass (class 424, subclass 94.6). Further, since the Examiner himself admits that Groups I, II, V and VI are all classified in the same place, consideration of these four groups together clearly would not place or induce burden on the Examiner.

The Examiner also maintains that the Inventions of groups IV, and I, II, V and VI (claims 51-63; and claims 1-18; claims 9-36 and 66-68; claim 64; and claim 65) are unrelated and represent separate inventions since the gene therapy method of Group IV is not suggested by the administration of an exogenous enzyme (i.e., lysosomal acid lipase), as used in Groups I, II, V and VI and accordingly, since the inventions of Groups I, II, IV, V and VI share no steps in common, these inventions are unrelated (MPEP §806.04 and §808.01). The inventions of groups I, II, V and VI all define methods of treatment using lysosomal acid lipase and pharmaceutical compositions thereof. These claims DO NOT distinguish between an exogenous or endogenous enzyme or require the lysosomal acid lipase to be an endogenous or exogenous enzyme. As previously stated, MPEP §803 indicates that even if a patent application contains independent and distinct inventions, those inventions should be considered together by the Examiner if he can do so without any undue burden.

Therefore, even assuming arguendo that the claims of inventions IV and I, II, V and VI do define five separate inventions, the Examiner can consider all of them without placing himself under an undue burden since they all relate to methods of treatment using lysosomal acid lipase and pharmaceutical compositions thereof. Therefore, the claims of inventions I, II, IV, V and VI of the present application should be considered together. A search of the use of lysosomal acid lipase, as described in inventions I, II, V and VI (claims 1-18, 19-36, 66-68, 64 and 65) would necessarily include a very large part of the search required for claims 51-63 (the invention of group IV, directed to gene therapy with the gene for lysosomal acid lipase).

Since several groups of claims can be considered together without placing any undue burden on the Examiner, the restriction requirement given by the Examiner, which attempts to define six separate inventions, is not appropriate in the present case. Accordingly, withdrawal of this restriction requirement is requested and issuance of an office action covering claims 1-51, 53-55, and 58-68 (inventions I, II, III, IV, V and VI) of the present application is earnestly requested.

In the event that the Examiner does not withdraw the restriction requirement and prosecute claims 1-51, 53-55, and 58-68 together, then at least Claims 1-18, 19-36 and 66-68; 64 and 65, (the Inventions of Groups I, II, V and VI) describing the methods of treatment using lysosomal acid lipase should be considered together in the present application (since by the Examiner's own admission they are classified in the same place).

If the Examiner will not allow this grouping of claims, then the Applicants request prosecution of the claims of Groups I and II (claims 1-18; and claims 19-36 and 66-68). These two groups are drawn to methods of reducing atherosclerotic

plaque and treating atherosclerosis, respectively, wherein atherosclerosis may be characterized by a build-up of atherosclerotic plaque. These methods are similar, utilizing essentially the same patents, and by the Examiner's own admission, the claims in these two groups may be classified in class 424, subclass 94.6.

Finally, if the restriction requirement of the present Office Action is maintained in full, then Applicants provisionally elect the claims of Group II, claims 19-36 and 66-68, for prosecution on the merits in the present application.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as EXPRESS MAIL in an envelope addressed to Box Non-Fee Amendment, The Assistant Commissioner for Patents, Washington, D.C., 20231, this 7th day of January, 2003.

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